510K) Summary of Safety and Effectiveness

FEB 14 2012

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter:

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Proprietary Name: Vital Signs Monitor Models M3 and M3A

Classification Name: 21 CFR 870.1130 Noninvasive blood pressure measurement system
21 CFR 870.2700, Oximeter
21 CFR 880.2910 Clinical electronic thermometer

Product code: DQA, DXN, FLL

Classification: Class II

Predicate Devices:

Manufacturer	Predicate Device	510(k) #
EDAN INSTRUMENTS, INC.	M3,M3A	K102835
RADIANT INNOVATION, INC.	THP59J	K111637

Device Description: M3 and M3A Vital Signs Monitor is a patient monitoring device providing the patient with a continuous vital physiological monitoring of non-invasive continuous monitoring of SpO2 (oxygen saturation of the blood), NIBP (non-invasive blood pressure) and TEMP (temperature). in a hospital, hospital type facilities environment and intra-hospital moves. The following lists the detailed features of the subject device.

- LCD or LED display
- SpO2, Pulse Rate NIBP and fast TEMP measurement
- Infrared ear temperature measurement
- Nellcor or EDAN SpO2 module
- Display numeric and waveform information simultaneously
- Nurse call feature
- Built-in Lithium-ion Battery

- Suitable for adult, pediatric and neonate patients
- Visual and audible alarm
- Trend graph review and record
- USB data storage and review
- Wired and wireless network capability

Comparison with predicate device

Monitoring unctions	Subject device	Predicated device
SpO2	yes	yes
Pulse Rate	yes	yes
Alarm feature	yes	yes
NIBP	yes	yes
Temperature	yes	yes

Intended Use:

The Vital Signs Monitor models M3 and M3A (hereinafter called monitor) is intended to be used for non-invasive continuous monitoring of SpO2 (oxygen saturation of the blood), NIBP (non-invasive blood pressure) and TEMP (temperature).

The monitor is intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in hospitals, hospital type facilities and intra-hospital moves.

The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both

Test Summary:

The following quality assurance measures were applied to the development of the Vital Signs Monitor Models M3 and M3A:

- Software testing
- Safety testing
- Performance testing
- Risk analysis
- Final validation

Conclusion:

Verification and validation testing were conducted on the Vital Signs Monitor Models M3 and M3A. This premarket notification submission demonstrates that Vital Signs Monitor Models M3 and M3A is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 14 2012

Edan Instruments, Inc.
c/o Mr. Randy Jiang
Certification Engineer
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CHINA 518067

Re: K120144
Trade/Device Name: Vital Signs Monitor, Models M3 and M3A
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Codes: DXN, DQA, FLL
Dated: January 16, 2012
Received: January 18, 2012

Dear Mr. Jiang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT #3

Indications for Use

510(k) Number (if known): K120144

Device Name: Vital Signs Monitor models M3 and M3A

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Prescription Use ✖ AND/OR Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120144